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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,633	10/22/2003	Michael D. West	38797-8005.US23	7608

22918 7590 08/01/2005

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EXAMINER	
LEWIS, PATRICK T	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,633	WEST ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 28-45 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims read upon pharmaceutical compositions comprising a non-polynucleotide inhibitor and the use of said compositions for inhibiting proliferation of immortalized, mammalian cells which have telomerase; however, the telomerase inhibitors of the instant invention are only described in functional terms. It is noted that while there are some working examples using certain nucleoside analogs, it is not seen as sufficient to support the breath of the claims. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. It is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to

describe how to obtain it. Functional descriptions of chemical compounds/compositions must be coupled with a known or disclosed correlation between function and structure. An adequate written description of a chemical invention also requires a precise definition such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed.

3. Claims 28-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting proliferation of immortalized, mammalian cells which have telomerase by administering an effective amount of GTO-12 to the cell and compositions comprising said GTO-12, does not reasonably provide enablement for a method of inhibiting proliferation of immortalized, mammalian cells which have telomerase by administering a compound other than GTO-12 nor is the disclosure enabled compositions effective to inhibit telomerase-mediated extension of telomeres in which GTO-12 is not present. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

1. the breadth of the claims;
2. the nature of the invention;
3. the state of the prior art;

4. the level of one of ordinary skill in the art;

5. the level of predictability in the art;

6. the amount of direction provided by the inventor;

7. the existence of working examples; and

8. the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 28, 30-33, and 35-51 are drawn to methods of inhibiting proliferation of immortalized, mammalian cells which have a telomerase comprising administering to the cells an effective amount of a non-polynucleotide inhibitor wherein the cells are leukemic or non-leukemic. Claims 29 and 34 are drawn to a pharmaceutical composition comprising a pharmaceutically acceptable buffer and an amount of a non-polynucleotide inhibitor of a mammalian telomerase.

Undue experimentation is required to determine which compounds would be useful as an inhibitor of telomerase to use for inhibiting the proliferation of various immortalized mammalian cells for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing such, as only a limited number of nucleoside analogs were assessed, out of the numerous nucleoside and nucleotide analogs known in the art, not to mention the near infinite number of other known compounds and classes of compounds. While it is noted that an assay has been described for identifying other telomerase inhibitors, without guidance as to what molecules would likely effect telomerase activity, undue trial and error experimentation would be required to screen through the myriad of different chemical

molecules to determine those with the desired telomerase inhibiting activity and that would function in the claimed method of inhibiting cellular proliferation.

It is noted that there is a great deal of unpredictability in the art. For example, various nucleoside and nucleotide analogs are known as inhibitors of polymerases such as reverse transcriptase, however, not all nucleoside and nucleotide analogs are inhibitors of polymerases. Further, there is no discernable pattern as to which nucleoside and nucleotide analog will inhibit a specific polymerase, such as reverse transcriptase, and in particular telomerase. The art al the time the invention was made fails to establish predictability with regard to the properties of the nucleosides and nucleotides analogs needed to perform the methods as instantly claimed. Greider et al. NATURE, 1989, Vol. 337, pages 331-336 (Greider) is representative of the state of the art at the time of the invention. Greider teaches the inhibition of telomerase activity by oligonucleotide **3** in either the presence or absence of RNase H; however, oligonucleotide **3** was the only nucleic acid assessed which showed inhibition of telomerase activity.

It is noted that while there are some working examples using certain nucleoside analogs, it is not seen as sufficient to support the breath of the claims. The instant specification is not seen to provide adequate guidance which would allow the skilled artisan to extrapolate from the disclosure and examples provided to enable the use of any other nucleoside analog, let alone a non-nucleoside analog, to inhibit telomerase activity in an immortalized mammalian cell. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's

alleged discovery, not how to find out how to use it for themselves. See *In re Gardner* et al. 166 USPQ 138 (CCPA 1970).

Conclusion

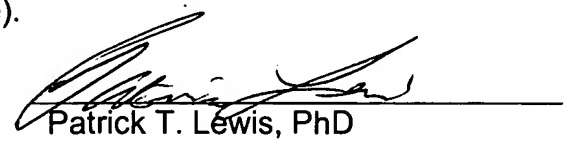
4. Claims 28-51 are pending. Claims 28-51 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick T. Lewis, PhD
Examiner
Art Unit 1623

ptl